

**UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION  
OPIATE LITIGATION

This document relates to:

*County of Lake, Ohio v. Purdue  
Pharma L.P., et al.,*  
Case No. 18-op-45032 (N.D. Ohio)

*County of Trumbull, Ohio v. Purdue  
Pharma, L.P., et al.,*  
Case No. 18-op-45079 (N.D. Ohio)

“Track 3 Cases”

**MDL No. 2804  
Case No. 17-md-2804  
Judge Dan Aaron Polster**

**DEFENDANTS’ MOTION FOR  
STAY PENDING APPEAL**

Defendants respectfully request a stay pending appeal of the Injunction Order (Dkt. 4611-1) and the Appointment Order (Dkt. 4652). The appointment of the Administrator and his staff—with intrusive and sweeping access to highly sensitive and private patient health information as well as to company employees, company files, company facilities, and even company computers—threatens irreparable harm to Defendants and third parties alike, imposes costs on Defendants that cannot be recouped, and creates a conflict with the neutral role of the Special Master.

On September 30, the Court entered an Appointment Order that specifies a broad array of powers for the Administrator of the Injunction Order. Dkt. 4652. The Appointment Order appoints as Administrator David R. Cohen, along with “Assistant Administrator” Michael J. Borden. *Id.* at 2. “As Administrator, Special Master Cohen has the authority to hire assistants and engage any legal, financial, accounting, investment, auditing, forecasting, and other advisors, consultants, independent contractors, and agents he deems necessary or appropriate.” *Id.* The Order states that Defendants must bear “100% of the cost” of the Administrator and the Assistant Administrator, including all costs and fees incurred by their “consultants and staff.” *Id.* at 6.

Among other things, the Order makes clear that the Administrator (and his potentially extensive staff) are empowered to “oversee compliance with all aspects of the Injunction Order” and to “direct, supervise, monitor, and report upon implementation and compliance with the Court’s Orders.” *Id.* at 2–3. The Order requires Defendants to “make readily available to the Administrator any and all individuals, information, documents, materials, programs, files, databases, services, facilities, and premises under their control that the Administrator requires to perform his duties,” necessarily including sensitive and protected health information in the prescription records of Defendants’ third-party patients. *Id.* at 7–8. Defendants also must make their “computer programs” available at the Administrator’s request. *Id.* In addition, the

Administrator “may require reports from any party in a format specified by the Administrator, as reasonably required to enable the Administrator to perform all assigned duties.” *Id.* at 8. The Order requires the “full cooperation” of the parties and their counsel.

Defendants should not have to bear these burdens—and the associated disruption to pharmacy practice and patient care—before the Sixth Circuit has a chance for review. As detailed below, it is unlikely that the unprecedented judgment in this case can withstand appellate review. Indeed, this Court has already recognized that this case involves “novel” and complex issues, Dkt. 4614 at 2, which supports the entry of a stay pending appeal before implementing a complicated injunctive remedy that might not be upheld.

Plaintiffs have effectively conceded that the equities do not require immediate imposition of injunctive terms. They reached settlements in these two Counties with two other pharmacies with substantial market share—pharmacies that were subject to the same adverse expert analyses of their opioid dispensing—without requiring any injunctive terms at all. The absence of negotiated injunctive terms in those earlier settlements belies any potential claim for urgency now. Nevertheless, last week’s order—appointing administrators and granting them, among other things, broad and unfettered authority to hire staff and consultants—effectively creates a judicially-supervised regulatory agency to oversee the injunctive terms that Defendants must start funding immediately. For these reasons and those below, a stay of the injunctive terms is warranted.<sup>1</sup>

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<sup>1</sup> This Court noted in its Appointment Order that Defendants had not—at that time—moved to stay the Injunction Order but had only moved to stay the monetary portion of the judgment. Dkt. 4652 at 3. Not only does the September 30, 2022, Appointment Order broaden the scope of the Injunction Order but Plaintiffs were on notice that a Motion to Stay the Injunction Order was contemplated and had stated that they “do and will oppose any attempt to stay execution of the portion of the judgment dealing with injunctive relief pending appeal.” Dkt. 4624 at 1 n.1. Defendants now seek a stay given the Appointment Order, which crystallizes and magnifies the irreparable harm the Injunction Order will impose on Defendants and third parties.

## **ARGUMENT**

To grant an injunction pending appeal under Rule 62(d), courts consider four factors: “(1) the likelihood that the party seeking the stay will prevail on the merits of the appeal; (2) the likelihood that the moving party will be irreparably harmed absent a stay; (3) the prospect that others will be harmed if the court grants the stay; and (4) the public interest in granting the stay.” *United States v. Cuthbertson*, No. 21cr486, 2021 WL 2952814, at \*2 (N.D. Ohio July 12, 2021); *see Mich. Coal. of Radioactive Material Users, Inc. v. Griepentrog*, 945 F.2d 150, 153 (6th Cir. 1991).

### **A. Defendants Are Likely to Succeed on Appeal.**

Although this Court has already rejected Defendants’ arguments on the merits, that is not dispositive; otherwise no district court would ever grant a stay pending appeal. Thus, “[m]any courts also take into account that the case raises substantial difficult or novel legal issues meriting a stay.” 11 Fed. Prac. & Proc. Civ. § 2904 & n.13 (3d ed. Apr. 2022 update); *NLRB v. Gen. Motors Corp.*, 510 F. Supp. 341, 342 (S.D. Ohio 1980) (granting stay due to “novel issues” even though court was “not persuaded that the Sixth Circuit . . . will reverse our decision”). Although the following is not an exhaustive list of issues on appeal, it suffices to show that Defendants have a strong likelihood of success, and that there are at the very least serious issues for the Sixth Circuit to consider.

#### **1. Plaintiffs’ nuisance claim is barred by the Ohio Product Liability Act.**

The Ohio Product Liability Act (“OPLA”) expressly “abrogate[s]” “any public nuisance claim or cause of action at common law in which it is alleged that the design, manufacture, supply, marketing, distribution, promotion, advertising, labeling, or sale of a product unreasonably interferes with a right common to the general public.” Ohio Rev. Code § 2307.71(A)(13), (B). This provision squarely applies here. Plaintiffs’ sole claim is a “public nuisance claim” alleging that

Defendants’ “supply,” “distribution,” and “sale of a product”—prescription pain medication—“interferes with a right common to the general public.” *Id.*; Am. Compl. ¶ 619.

The Ohio legislature enacted this portion of the OPLA to overturn a decision of the Ohio Supreme Court that had allowed a nuisance claim based on the sale of firearms. *See Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136 (Ohio 2002). By overturning that decision, the Ohio legislature joined the “clear national trend” that has rejected “products-based public nuisance claims.” *State ex rel. Hunter v. Johnson & Johnson*, 499 P.3d 719, 729–30 (Okla. 2021) (prescription opioids); *see also, e.g., Tioga Pub. Sch. Dist. No. 15 of Williams Cnty. v. U.S. Gypsum Co.*, 984 F.2d 915, 920 (8th Cir. 1993) (asbestos); *City of Bloomington v. Westinghouse Elec. Corp.*, 891 F.2d 611, 614 (7th Cir. 1989) (firearms); *City of Huntington v. AmerisourceBergen Drug Corp.*, ---F. Supp. 3d---, 2022 WL 2399876, at \*56–59 (S.D. W. Va. July 4, 2022) (prescription opioids).

As these courts have recognized—and as the Ohio legislature agreed—allowing product-based nuisance claims would distort the common law of nuisance by eliminating many of its traditional elements. It would also upend centuries of product-liability law, transforming the once-narrow nuisance tort into “a monster that would devour in one gulp the entire law of tort.” *Tioga*, 984 F.2d at 921. That is exactly what the Ohio legislature sought to avoid when it abrogated “any public nuisance claim” based on the “sale of a product.” Ohio Rev. Code § 2307.71(A)(13), (B). Judge Ruiz, then still acting as a Magistrate Judge, thus held that “the plain language of the statute” abrogated the claim asserted by Plaintiffs. Dkt. 1025 at 64.

This Court, however, rejected Judge Ruiz’s analysis and held that the OPLA bars nuisance claims only if they seek “compensatory damages,” not “equitable relief” such as abatement. Dkt. 1203 at 26. Respectfully, the Sixth Circuit is likely to disagree. While a separate paragraph of the

OPLA abrogates claims seeking “compensatory damages,” Ohio Rev. Code § 2307.71(A)(13)(a)–(c), the definition of abrogated claims “also includes” “*any* public nuisance claim” at common law. *Id.* § 2307.71(A)(13) (emphasis added). Plaintiffs’ common-law “public nuisance claim,” “seek[ing] abatement,” “is [thus] expressly subsumed by the OPLA.” *City of Toledo v. Sherwin-Williams Co.*, No. CI 200606040, 2007 WL 4965044 (Ohio Ct. Com. Pl. Dec. 12, 2007).

## 2. The liability ruling rests on a misreading of federal law.

The Court’s decision also is likely to be overruled because it rests on a flawed reading of the Controlled Substances Act (CSA) and its implementing regulations. The Court held that the CSA imposes an affirmative duty on pharmacy owners to proactively aggregate and analyze data to try to identify invalid prescriptions and prevent them from being filled. *See* Dkt. 3499 at 5. In reaching this conclusion the Court relied primarily on two CSA regulations, but neither one of them actually imposes any of the affirmative obligations that the Court perceived.

The first regulation prohibits a “pharmacist” from “knowingly filling” an opioid prescription that was not “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 C.F.R. § 1306.04(a). Even if pharmacy companies like Defendants, as opposed to pharmacists, could be liable under that provision, there was no evidence in the entire case that any pharmacist employed by any Defendant ever filled any prescription knowing it to be illegitimate. There was thus no violation of § 1306.04, and the verdict could not properly have rested on such a finding.

The second regulation, relating to “Security [R]equirements,” requires pharmacies to provide “effective controls and procedures to guard against theft and diversion,” *id.* § 1301.71(a). But the very next sentence expressly defines what those “effective controls” must be, incorporating a series of neighboring provisions that require various security measures. *Id.*; *see, e.g., id.* § 1301.75 (“stor[ing]” opioids in a certain way). Defendants did not even *allegedly* violate any of

those rules here. And beyond those rules, § 1301.71 does not create any affirmative legal duty to aggregate patient and prescriber data to detect illegitimate prescriptions in order to “guard against theft and diversion.” So there was no violation of § 1301.71 either.

**3. The liability ruling punishes lawful dispensing.**

Alternatively, the Court permitted Plaintiffs to argue—and the jury to find—that Defendants were liable even if they had fully complied with federal and state law—i.e., even if they were filling legitimate prescriptions written by legitimate doctors seeking to treat legitimate patients for legitimate medical conditions, and even if they followed the proper procedures in doing so. The Court effected this theory of liability by declining to include in its instructions on the “intentional” conduct prong of public nuisance any requirement that the conduct violate any of the rules and regulations governing the filling of prescriptions. It then permitted Plaintiffs to argue to the jury that Defendants could be liable even if their dispensing was “superb.” The Court’s instructions effectively read out the well-established requirement that conduct underlying a nuisance be unreasonable, and it simultaneously overrode the balance struck by the Controlled Substances Act to ensure patients can obtain the medicine they need. The Court’s finding that a pharmacy can be subject to hundreds of millions of dollars in liability for filling legitimate prescriptions for lawful medications, and while following the law, is likely to be reversed.

**4. Defendants did not proximately cause the opioid crisis.**

The Sixth Circuit is also likely to reverse due to the lack of proximate cause. “[P]roximate cause ‘generally bars suits for alleged harm that is “too remote” from the defendant’s unlawful conduct.’” *Bank of Am. Corp. v. City of Miami*, 137 S. Ct. 1296, 1306 (2017); *see also Pendrey v. Barnes*, 479 N.E.2d 283, 284 (Ohio 1985).

The Sixth Circuit has twice affirmed dismissals for lack of proximate cause in similar cases imposing unconventional public nuisance liability for broad-based social problems (both involving

banks that allegedly stoked financial crises and associated societal problems). In both cases, applying Ohio law, the Sixth Circuit held there was a lack of proximate cause because the alleged harms were too remote from the defendants' conduct. *City of Cincinnati v. Deutsche Bank Nat'l Tr. Co.*, 863 F.3d 474, 480–81 (6th Cir. 2017); *City of Cleveland v. Ameriquest Mortg. Sec., Inc.*, 615 F.3d 496, 502 (6th Cir. 2010). The same result is likely here, where “so many independent actors” “unconnected to the Defendants' conduct” form a long causal chain before leading to Plaintiffs' purported increased costs in combating the opioid crisis. *Ameriquest*, 615 F.3d at 504–05; *see* Dkt. 4064, Oct. 21 trial tr., vol. 13, at 3558 (admitting as much).

### **5. Juror misconduct requires a new trial.**

The Sixth Circuit is likely to vacate the judgment and order a new trial because of what this Court acknowledged to be the “huge problem” of “serious” juror misconduct. Dkt. 4065, Oct. 22 trial tr., vol. 14, at 3716, 3720. A juror violated what this Court called “probably the most important instruction” by conducting outside internet research on a disputed issue in the case, printing out the results of that research, making it available to every other juror, and discussing it in the jury room. Dkt. 4068 at 2–3; *see also* Dkt. 4067-1; Dkt. 4065, Oct. 22 trial tr., vol. 14, at 3718–21. This research was meant to and likely did bolster one of Plaintiffs' primary (and contested) trial themes: that the Defendant pharmacies prioritized profit over public health. Plaintiffs' own counsel initially acknowledged, under his “ethical obligation” of “candor to the tribunal,” that a mistrial was “appropriate” because the misconduct “affects this jury” and “affects everybody whether they recognize it or not.” Dkt. 4065, Oct. 22 trial tr., vol. 14, at 3769–70. Rightfully so. The Sixth Circuit “has not hesitated to declare mistrials” where misconduct by a juror “injected extraneous information into the trial” that pertains to an important disputed issue, and the juror's act was “a response to the facts of the case at hand.” *In re Beverly Hills Fire Litig.*,



695 F.2d 207, 213–14 (6th Cir. 1982). This “can rarely be viewed as harmless,” *Nian v. Warden, N. Cent. Corr. Inst.*, 994 F.3d 746, 758 (6th Cir. 2021), and it was not harmless here.

**B. The Balance of Equities and the Public Interest Favor a Stay.**

Nor do the equities support immediate imposition of the Court’s injunctive terms.

*First*, there is no evidence that the injunction taking immediate effect will provide any practical benefits. Plaintiffs have never contended that Plaintiffs’ systems are not working to ensure proper dispensing in their *current* form, as the trial focused on past practices largely from over a decade ago. Indeed, Plaintiffs did not require any sort of injunctive agreement when settling exactly the same nuisance claims with two other pharmacy chains without requiring any injunctive relief. Those chains—Giant Eagle and Rite Aid—were responsible for a significant volume of opioid dispensing in the counties, *see* CVS-MDL-05013; CVS-MDL-05014, and were subject to exactly the same expert analyses and opinions regarding Plaintiffs’ allegations about their dispensing conduct. Had injunctive terms been crucial to the public interest, the counties would have insisted on them as a condition of their settlements with Giant Eagle and Rite Aid.

*Second*, no witness testified (and no other evidence was introduced suggesting) that the injunctive terms were necessary to alleviate any harm currently being suffered in the counties. In fact, not one witness opined on the effect, if any, the injunctive terms would have on the counties—especially in light of the policies and procedures each Defendant already has in place and the fact that most pharmacies in the counties are not even subject to them.

*Third*, the terms of the Appointment Order afford the Administrator and his staff access to Protected Health Information pertaining to medical prescriptions of thousands of third-party patients. Defendants and others currently take—and are legally required to take—extraordinary steps to protect such confidential information. But the Appointment Order imposes no such safeguards. And neither the Administrator nor his Assistant have the ability to handle such

sensitive information appropriately in a world in which wrongdoers are constantly looking to exploit gaps in the most sophisticated information security systems, to say nothing of those maintained by individuals like the proposed Administrator and his Assistant.<sup>2</sup> Not only Defendants, but also third parties and the public, have a strong interest in preventing the disclosure of Protected Health Information and other sensitive information under the Appointment Order.

**C. Defendants Will Suffer Irreparable Harm Without a Stay.**

Without a stay, Defendants will suffer irreparable harm that cannot be remedied even if they prevail on appeal.

*First*, the oversight and enforcement powers of the Administrator will compromise the confidentiality of sensitive information in Defendants' possession, including, but not limited to, third-party patient Protected Health Information. The powers of the Administrator and his staff to examine Defendants' internal files, documents, and materials pertaining to their dispensing practices and patients will inevitably intersect with private and confidential medical information, which should not be disclosed or shared as contemplated by the Court's orders.

*Second*, absent a stay, complying with the Administrator's demands and paying the fees of the Administrator, Assistant Administrator, and their staff will impose substantial costs that will be impossible for Defendants to recover. The Injunction Order expressly provides that "[t]he Administrator's fees will be paid by Defendants." Dkt. 4611-1, § I.B; *see also* Dkt. 4652 at 6 (making clear that Defendants must pay "100% of the cost"). This cost will likely be significant, as the Administrator and his assistant are also empowered to hire additional "assistants" as well as whatever "legal, financial, accounting, investment, auditing, forecasting, and other advisors,

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<sup>2</sup> These risks are not hypothetical, as federal courts themselves have suffered serious breaches. *See* Alexandra Jones, *Feds Working to Uncover Full Scope of Court System Data Breach*, Courthouse News Service (July 28, 2022), <https://tinyurl.com/yv5zra25>.

consultants, independent contractors, and agents he deems necessary or appropriate.” Dkt. 4652 at 2. The Track 3 case and the Abatement Order are expressly limited to the two Counties, as they must be. The Appointment Order should also be so limited, but because it lacks the same express limitations on the access it provides the Administrator, it threatens additional burden and cost on Defendants—indeed, on October 3, Mr. Cohen reached out to Defendants and asked them to explain which elements of the Order are already being implemented “on a national level.” Practically speaking, Defendants have no means of recouping the costs of paying for all the work that the Administrator and all of his staff members, assistants, consultants, and other professionals will perform, even if the Sixth Circuit ultimately determines that none of those costs were warranted in the first place.<sup>3</sup>

As the Supreme Court recently held, such unrecoverable costs are irreparable harm when there is “no guarantee of eventual recovery.” *Ala. Ass’n of Realtors v. Dep’t of Health & Hum. Servs.*, 141 S. Ct. 2485, 2489 (2021); *see also, e.g., NFIB v. OSHA*, 142 S. Ct. 661, 666 (2022) (irreparable harm based on “unrecoverable compliance costs”). Other courts, too, have recognized irreparable harm when “[n]o mechanism . . . exists for [parties] to recover the compliance costs they will incur if the [injunction is reversed].” *Texas v. EPA*, 829 F.3d 405, 434 (5th Cir. 2016); *see also, e.g., BST Holdings, L.L.C. v. OSHA*, 17 F.4th 604, 618 (5th Cir. 2021); *In re MCP No. 165*, 21 F.4th 357, 400 (6th Cir. 2021) (Larsen, J., dissenting) (“unrecoverable compliance costs” count as “irreparable” harm) (majority opinion reversed by the Supreme Court); *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 220–21 (1994) (Scalia, J., concurring in part and concurring in the judgment) (“nonrecoverable compliance costs” are quintessential “irreparable harm”).

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<sup>3</sup> At the very least, if the Court does not grant a stay, it should require Plaintiffs to post a bond to cover the injunction-related costs that Defendants will incur while the appeal is pending.

*Finally*, the appointment of Special Master Cohen to serve simultaneously as the Administrator of the Injunction Order (not to mention administrator of the Common Benefit Fund) creates a conflict of interest. It is well settled that this type of conflict of interest is a form of irreparable harm. *See, e.g., In re Bulger*, 710 F.3d 42, 49 (1st Cir. 2013) (finding irreparable harm when it was “clear that a reasonable person might question the judge’s ability to preserve impartiality”); *Cobell v. Norton*, 334 F.3d 1128, 1139 (D.C. Cir. 2003) (“When the relief sought is recusal of a disqualified judicial officer . . . the injury suffered by a party required to complete judicial proceedings overseen by that officer is by its nature irreparable.”). Here, the appointment of the Special Master as the Administrator creates irreparable harm in two ways.

Most fundamentally, those with personal knowledge of matters in a case are disqualified from being neutral judicial arbiters. *See* Code of Conduct for United States Judges, Canon 3(C)(1)(a) (judge should recuse if he has personal knowledge of disputed evidentiary fact); *see, e.g., Cobell*, 334 F.3d at 1144 (“involvement in this case as Court Monitor would cause a reasonable person to doubt his ability to remain impartial while serving as Special Master”). Mr. Cohen’s broad access to Defendants’ employees, facilities, systems, and files in his role as Administrator (Dkt. 4652 at 7–8) will give him firsthand, personal knowledge that is inappropriate for a Special Master to have—especially one like Special Master Cohen who decides the scope of the discovery, makes trial rulings, assists in the decision of dispositive motions, drafts jury instructions, and regularly meets with and works hand in hand with the presiding judge. This is a bell that cannot be unrung.

Moreover, in his capacity as Special Master, Mr. Cohen is supposed to serve as a neutral adjunct to the court in assisting with the impartial resolution of disputes among the parties in the MDL. *See, e.g., In re Brooks*, 383 F.3d 1036, 1046 (D.C. Cir. 2004) (A special master cannot serve

in a case in which “an observer apprised of all the facts would reasonably question his impartiality.”). But now, as Administrator of the injunction, Mr. Cohen’s role is to “direct, supervise, monitor, and report upon implementation and compliance with the Court’s Orders,” including the terms of the injunction that the Court has entered for Plaintiffs’ benefit. That role cannot be reconciled with his role as Special Master.<sup>4</sup>

### **CONCLUSION**

The Court should stay the Injunction Order and Appointment Order pending appeal. At the least, “a temporary stay” is warranted so Defendants can “seek and obtain . . . a stay” at the Sixth Circuit. *United States v. Salim*, No. 15-cr-358, 2018 WL 1138287, at \*3 (N.D. Ohio Mar. 2, 2018).

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<sup>4</sup> The same conflicts exist for Mr. Borden, who serves as an assistant to Mr. Cohen both as Special Master and as Administrator.

Dated: October 5, 2022

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on October 5, 2022, I electronically filed the foregoing document with the Clerk of the Court by using the CM/ECF system, which will send notification of such filing to all counsel of record at their e-mail addresses on file with the Court.

Dated: October 5, 2022

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